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6 **UNITED STATES DISTRICT COURT**
7 **DISTRICT OF ARIZONA**
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10 **Lori Spellman,**)
11 **Plaintiff,**) **3:16-cv-08080 JWS**
12 **vs.**) **ORDER AND OPINION**
13 **Smith & Nephew, Inc.,**) **[Re: Motion at Docket 24]**
14 **Defendant.**)
15 _____)
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17 **I. MOTION PRESENTED**

18 At docket 24 plaintiff Lori Spellman (“Spellman”) moves pursuant to Federal Rule
19 of Civil Procedure 15(a)(2) for leave to file an amended complaint. Defendant Smith &
20 Nephew, Inc. (“S&N”) opposes at docket 27. Spellman replies at docket 28. Oral
21 argument was requested but would not assist the court.
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23 **II. BACKGROUND**

24 Spellman brought strict liability and negligence claims against S&N in April 2016
25 based on injuries that were allegedly caused by S&N’s Birmingham Hip Resurfacing
26 (“BHR”) system, a metal-on-metal hip resurfacing prosthesis that was implanted in both
27 of her hips. Spellman’s original complaint alleged that S&N is liable for violating the
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1 Federal Food, Drug, and Cosmetic Act” (“FDCA”)¹ and a laundry list of federal
2 regulations,² but it did not connect any of the alleged violations to any specific facts.
3 The court dismissed Spellman’s complaint without prejudice at docket 23, holding that
4 Spellman’s complaint lacked any factual enhancement to push her allegations across
5 the line that separates possibility and plausibility.³
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7 Spellman moves for leave to file an amended complaint and submits a proposed
8 amended complaint (“AC”) at docket 24-1. Spellman now alleges that S&N not only
9 violated the FDCA and related federal regulations, but also the FDA’s Approval Order
10 (“Approval Order”).⁴ The AC states that these violations are “evident” based on thirteen
11 actions that Spellman describes as S&N’s “malfeasance, misfeasance, and/or
12 nonfeasance.”⁵
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15 **III. STANDARD OF REVIEW**

16 Rule 15(a) states that after the time to amend pleadings as a matter of course
17 has expired, “a party may amend its pleading only with the opposing party’s written
18 consent or the court’s leave.” “[T]he grant or denial of an opportunity to amend is within
19 the discretion of the District Court,”⁶ and the “court should freely give leave when justice
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22 ¹21 U.S.C. § 301, *et seq.*

23 ²Doc. 1 at 4 ¶¶ 12–13; 8 ¶¶ 21–22.

24 ³Doc. 23 at 7–8 (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 557 (2007)).

25 ⁴Doc. 24-1 at 8 ¶ 19; 14 ¶ 30.

26 ⁵*Id.* at 9 ¶ 21; 16 ¶ 31.

27 ⁶*Foman v. Davis*, 371 U.S. 178, 182 (1962).
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1 so requires.”⁷ Although “Rule 15’s policy of favoring amendments to pleadings should
 2 be applied with ‘extreme liberality,’”⁸ the court “need not grant leave to amend where
 3 the amendment: (1) prejudices the opposing party; (2) is sought in bad faith;
 4 (3) produces an undue delay in litigation; or (4) is futile.”⁹ S&N argues that Spellman’s
 5 proposed amendment is futile. “Futility of amendment can, by itself, justify the denial of
 6 a motion for leave to amend.”¹⁰
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8 A district court may deny a proposed amendment as futile where it “could not
 9 withstand a motion to dismiss.”¹¹ Thus, the standard of review under Rule 12(b)(6) may
 10 be relevant to a Rule 15(a) motion. Under Rule 12(b)(6), “[a]ll allegations of material
 11 fact in the complaint are taken as true and construed in the light most favorable to the
 12 nonmoving party.”¹² To be assumed true, the allegations “may not simply recite the
 13 elements of a cause of action, but must contain sufficient allegations of underlying facts
 14 to give fair notice and to enable the opposing party to defend itself effectively.”¹³
 15 Dismissal for failure to state a claim can be based on either “the lack of a cognizable
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20 ⁷Fed. R. Civ. P. 15(a)(2).
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22 ⁸*United States v. Webb*, 655 F.2d 977, 979 (9th Cir. 1981) (quoting *Rosenberg Bros. & Co. v. Arnold*, 283 F.2d 406, 406 (9th Cir. 1960)).

23 ⁹*AmerisourceBergen Corp. v. Dialysist W., Inc.*, 465 F.3d 946, 951 (9th Cir. 2006).
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25 ¹⁰*Bonin v. Calderon*, 59 F.3d 815, 845 (9th Cir. 1995).
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27 ¹¹*Glick v. Koenig*, 766 F.2d 265, 268 (7th Cir. 1985). See also *Jones v. Cmty. Redevelopment Agency of City of Los Angeles*, 733 F.2d 646, 650 (9th Cir. 1984).
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¹²*Vignolo v. Miller*, 120 F.3d 1075, 1077 (9th Cir. 1997).

¹³*Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011).

1 legal theory or the absence of sufficient facts alleged under a cognizable legal theory.”¹⁴
2 “Conclusory allegations of law . . . are insufficient to defeat a motion to dismiss.”¹⁵
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4 To avoid dismissal, a plaintiff must plead facts sufficient to “state a claim to relief
5 that is plausible on its face.”¹⁶ “A claim has facial plausibility when the plaintiff pleads
6 factual content that allows the court to draw the reasonable inference that the
7 defendant is liable for the misconduct alleged.”¹⁷ “The plausibility standard is not akin
8 to a ‘probability requirement,’ but it asks for more than a sheer possibility that a
9 defendant has acted unlawfully.”¹⁸ “Where a complaint pleads facts that are ‘merely
10 consistent with’ a defendant’s liability, it ‘stops short of the line between possibility and
11 plausibility of entitlement to relief.’”¹⁹ “In sum, for a complaint to survive a motion to
12 dismiss, the non-conclusory ‘factual content,’ and reasonable inferences from that
13 content, must be plausibly suggestive of a claim entitling the plaintiff to relief.”²⁰
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21 ¹⁴*Balistreri v. Pacifica Police Dep’t*, 901 F.2d 696, 699 (9th Cir. 1990).

22 ¹⁵*Lee v. City of Los Angeles*, 250 F.3d 668, 679 (9th Cir. 2001).

23 ¹⁶*Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570).

24 ¹⁷*Id.*

25 ¹⁸*Id.* (citing *Twombly*, 550 U.S. at 556).

26 ¹⁹*Id.* (quoting *Twombly*, 550 U.S. at 557).

27 ²⁰*Moss v. U.S. Secret Serv.*, 572 F.3d 962, 969 (9th Cir. 2009); *see also Starr*, 652 F.3d
28 at 1216.

IV. DISCUSSION

A. Spellman's New, Conclusory Allegations Are Insufficient to State a Claim

As factual support for her claims, Spellman now asserts that S&N:

- 1.) "allowed and encouraged its commission-based salesmen to not report adverse events and complaints such as revision surgeries . . .";
- 2.) "willfully ignored the existence of numerous adverse events and complaints, such as revision surgeries, which it knew or should have known were not being reported to the company or the FDA;"
- 3.) "received hundreds of adverse reports regarding the BHR system but delayed its [sic] reporting to the FDA;"
- 4.) "failed to properly communicate adverse events to the FDA, when it did report them, and when doing so, wrongly attempted to blame others for the adverse events;"
- 5.) "failed to analyze the adverse events and revision surgeries of which it was aware to determine why so many revisions were required so soon after implantation;"
- 6.) "failed to investigate and report on unanticipated events;"
- 7.) "failed to investigate all Device Failures;"
- 8.) "failed to revise its instructions to doctors and its surgical techniques documents to reflect the true problematic experience with the BHR;"

- 1 9.) “failed to disclose that some of the surgeons . . . upon whose data it relied
2 to boast a high success rate for the BHR had been bribed or paid financial
3 kickbacks or illegal averments and remuneration in order to use the BHR;”
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- 5 10.) “willfully ignored the existence of numerous complaints about failures
6 associated with components of the BHR that were being used in illegal
7 combinations throughout the United States;”
8
- 9 11.) “failed to properly train all surgeons and Original Core Surgeons using the
10 product;”
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- 12 12.) “misrepresented to the surgeons in the United States that *in vivo* testing of
12 the BHR had been undertaken;” and
13
- 14 13.) “failed to timely supplement its labeling as required in the Approval Order
15 with information pertaining to the various failures of the BHR system.”
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16 Spellman offers no supporting facts or evidence for any of these assertions.

17 As the court stated in its previous order, courts employ a two-step process when
18 analyzing whether a complaint’s allegations satisfy Rule 8(a).²¹ First, they “identify[]
19 pleadings that, because they are no more than conclusions, are not entitled to the
20 assumption of truth.”²² If the court identifies well-pleaded factual allegations, it
21 proceeds to the next step, under which it assumes the veracity of the allegations and
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26 ²¹*Eclectic Properties E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 995–96 (9th Cir.
27 2014).

28 ²²*Iqbal*, 556 U.S. at 679.

determines “whether they plausibly give rise to an entitlement to relief.”²³ Spellman’s complaint again fails at the first step.

Spellman’s new, conclusory allegations are insufficient to state a claim.²⁴ “A complaint will not survive a motion to dismiss if it ‘tenders naked assertions devoid of further factual enhancement.’”²⁵ The conclusory nature of Spellman’s new assertions is particularly troubling because Spellman knew from the court’s previous order that she needed to allege non-conclusory facts in order to revive her case. Instead of doing so, she doubled down with even more naked assertions. The court cannot determine whether Spellman is unwilling or unable to state well-pleaded claims against S&N, but it is clearly one or the other. Spellman’s motion for leave to file an amended complaint is denied as futile.

V. CONCLUSION

Based on the preceding discussion, the plaintiff’s motion at docket 24 is DENIED with prejudice.

DATED this 3rd day of February 2017.

/s/ JOHN W. SEDWICK
SENIOR JUDGE, UNITED STATES DISTRICT COURT

²³*Id.*

²⁴*Blantz v. California Dep’t of Corr. & Rehab., Div. of Corr. Health Care Servs.*, 727 F.3d 917, 927 (9th Cir. 2013).

²⁵*Id.* (quoting *Iqbal*, 556 U.S. at 678). See also *Eclectic Properties E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 999 (9th Cir. 2014) (court declined to accept the complaint’s conclusory assertion of the market value of property because the complaint did “not cite any documents or sources for this value, nor [did] it explain the methodology by which this value was derived.”); *Cook v. Brewer*, 637 F.3d 1002, 1008 (9th Cir. 2011) (same).